

### **DETAILED ACTION**

The examiner acknowledges receipt of IDS filed 4/15/09, amendment to the specification and claims and remarks filed 3/12/09. Claim 1 is canceled. Claims 33-36, 56, 64 and 69 are currently amended. Claims 33-78 are pending.

In response to applicant's request for acknowledgment of priority claim, the examiner acknowledges this application as a 371 application of PCT/GB03/00131 filed 01/16/2003. Receipt is also acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Specification***

1. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Page 2, line 24 of the specification contains browser executable link.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 33-37, 41-55, 64 and 67-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description.

5. Claim 1 is directed to a process in which zwitterionic monomer I is polymerized in a living radical polymerization process in the presence of catalyst and initiator. There is no description for the product made by the process and the claims have not identified the polymer product formed. The claim has been amended to say that the process forms a compound that is conjugate of a polymer and a biologically active moiety. However, the claim does not say what the product is that is formed and one cannot make what one does not know.

It is suggested that applicant name the product made without introducing new matter into the claims and/or specification.

Applicant indicates that the amendment to claim 33 provides written description for the product formed and the examiner disagrees because “forming a compound which is a conjugate of a polymer and a biologically active moiety” is not a description for what product is formed.

6. Claims 33-37, 41-55, 64 and 67-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 33 appears to be forming a compound that has a biological moiety conjugated to a polymer. However, the initiator defined as formula V has R13 that is selected from biologically

active group substituted alkyl .... It is unclear how the substituted biological moiety initiates the polymerization and conjugates to the polymer.

8. Claim 33 defines the initiator as formula V. Claim 34 depends on claim 33 and defines also initiator VI. It is unclear how claim 34 can define another initiator when the independent claim has defined initiator V. Thus claim 34 improperly depends on claim 33.

It would appear that claim 33 can select the initiator from formula V and VI so that claim 34 would then properly limit the initiator to formula VI.

9. Claim 34 recites the dependency from claim 33 three times.

In this case, it is suggested that the dependency from claim 33 be recited once, wherein Y is  $Y^1$  and  $R^{43}$  is  $R^{13}$ .

10.  $R^{43}$  is defined in the specification at page 6 and  $R^{43}$  is not the same as  $R^{13}$  according to the definition for  $R^{13}$  provided on page 5 of the specification. It is thus unclear how claim 34 equates  $R^{43}$  to  $R^{13}$ .  $R^{43}$  is a biologically active moiety (page 6 of specification) and  $R^{13}$  is biologically active group substituted alkyl, etc (claim 33 and page 5 of the specification).

11. Claim 68 is unclear because  $W^+$  is defined as a group of compounds and it is unclear how the  $W^+$  could be all those compounds when the phosphonium in claim 44 is considered. It appears that applicant intended to select  $W^+$  from the list of compounds in claim 68.

12. Claim 68 defines "Het" as an aromatic nitrogen phosphorus or sulfur containing ring. Applicant has also not defined what an aromatic nitrogen is, for example.

13. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v.*

*HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term “aromatic nitrogen-, phosphorous-, or sulfur ” in claim 68 is used by the claim to mean “Het”, while the accepted meaning is “nitrogen or phosphorous or sulfur containing aromatic ring. The term is indefinite because the specification does not clearly redefine the term. Thus, stating that nitrogen is aromatic is contrary to the meaning of nitrogen.

14. Prior art Rejections: Upon further consideration of the claims and as articulated to applicant's representative, prior art rejections are withdrawn and new prior art rejections are not made because there is a great deal of confusion and uncertainty in the interpretation of the claims that art rejection of the claims as currently presented may be speculative. Therefore, the rejection under 35 USC 112, 1<sup>st</sup> and 2<sup>nd</sup> may afford the applicant a better appreciation for relevant prior art if the claims are redrafted to clarify the claims and to take care of the issue raised under 35 USC 112, 1st. Therefore, response to applicant's arguments with respect to Haddleton, Davies and the provisional double patenting rejections has not been addressed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/  
Examiner, Art Unit 1618